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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,844	01/26/2006	Jadwiga Bienkowska	ARS-110	2201

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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
03/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,844	BIENKOWSKA ET AL.	
	Examiner	Art Unit	
	JON M. LOCKARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 42-44, 47, 48-50 (each in part), in so far as they are drawn to polypeptides and fusions thereof and compositions comprising the same, nucleic acids, vectors and host cells comprising said nucleic acid molecules and compositions comprising the same, a method for recombinantly producing the polypeptide, and a method for determining the activity and/or presence of the polypeptide in a sample.

Group II, claim(s) 42, 45-46, and 49 (each in part), in so far as they are drawn to antagonists, and compositions comprising the same.

Group III, claim(s) 42 and 49 (each in part), in so far as they are drawn to agonists, and compositions comprising the same.

Group IV, claim(s) 42, 43, and 49 (each in part), in so far as they are drawn to peptide mimetics, and compositions comprising the same.

Group V, claim(s) 42 (in part), in so far as it is drawn to a transgenic organism or cell thereof.

Group VI, claim(s) 42-43 and 49 (each in part), in so far as they are drawn to a compound of undisclosed constitution which enhances the expression of a polypeptide, and compositions comprising the same.

Group VII, claim(s) 42-43 and 49 (each in part), in so far as they are drawn to compounds of undisclosed constitution which reduces the expression of a polypeptide, and compositions comprising the same.

Group VIII, claim(s) 49 and 52-53 (each in part), in so far as they are drawn to a method of treatment comprising administering a polypeptide.

Group IX, claim(s) 49-50 and 52-53 (each in part), in so far as they are drawn to a method of treatment comprising administering a nucleic acid.

Group X, claim(s) 49 and 52-53 (each in part), in so far as they are drawn to a method of treatment comprising administering an antagonist.

Group XI, claim(s) 49 and 52-53 (each in part), in so far as they are drawn to a method of treatment comprising administering an agonist.

Group XII, claim(s) 49 and 52-53 (each in part), in so far as they are drawn to a method of treatment comprising administering a peptide mimetic.

Group XIII, claim(s) 49 and 52-53 (each in part), in so far as they are drawn to a method of treatment comprising administering a compound of undisclosed constitution which enhances the expression of a polypeptide.

Group XIV, claim(s) 49 and 52-53 (each in part), in so far as they are drawn to a method of treatment comprising administering a compound of undisclosed constitution which decreases the expression of a polypeptide.

Group XV, claim(s) 49 and 55 (each in part), in so far as they are drawn to a method for screening/identifying candidate compounds utilizing a polypeptide.

Group XVI, claim(s) 49-50 and 54-55 (each in part), in so far as they are drawn to a method for screening/identifying candidate compounds utilizing a nucleic acid.

Group XVII, claim(s) 49 and 54 (each in part), in so far as they are drawn to a method for screening/identifying candidate compounds utilizing a transgenic organism or cell thereof.

Group XVIII, claim(s) 49 and 56 (each in part), in so far as they are drawn to a method for determining the presence or amount of a transcript or a nucleic acid.

2. The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pursuant to 37 C.F.R. § 1.475(B-D), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product, an isolated polypeptide, the method of making the polypeptide, and the first recited use of the polypeptide. Because the technical features of the Groups II-XVIII inventions is not present in the Group I claims, unity of invention is lacking. Furthermore, the polypeptides of Group I, the antagonists of Group II, the agonists of Group III, the peptide mimetics of Group IV, the transgenic organism of Group V, the compounds of undisclosed constitution which enhance the expression of a polypeptide of

Group VI, and the compounds of undisclosed constitution which decrease the expression of a polypeptide of Group VII, are structurally and functionally different chemical compounds, each of which can be made and used without the other compound, or in the case of the transgenics, an organism. The methods of Groups VIII-XVIII require compounds, which are structurally and functionally different from each other, and each can be made and used without the other. Lack of unity is shown because these compounds and the methods utilizing them lack a common utility which is based upon a common technical feature which has been identified as the basis for that common utility.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

4. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

7. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon M. Lockard, Ph.D.
March 26, 2008

/Jon M Lockard/
Examiner, Art Unit 1647